05.11.2024

Digitally signed by Lazari Cristina
Date: 2024.11.08 14:23:00 EET
Reason: MoldSign Signature
Location: Moldova

To: Center for Centralized Public Procurement in Health

Re: **Tender no.** ocds-b3wdp1-MD-1728632585871 **from 12.11.2024**

Lot.I Letter of Confirmation

Herewith, we Roche Diagnostics express our respect and thankfulness for your interest in Roche's high-quality diagnostic equipment in the blood safety area.

Following to the tender request, we would like confirm the following:

1.The offer for lot I includes:

All needed test/ accessories / consumables / reagents / calibrators / controls / solutions and other mandatory products to perform the contracted quantity of tests on **cobas pro e801 instrument;**

1.1 Requirements for Regents:

a) stability when placed in the medical device for at least 28 days up to 4 months;

b) provided by the manufacturer with protection elements against evaporation and leakage.

1.2 Consumables Requirements:

a) non-reusable assay tips and cups;

b) ensures a high degree of accuracy and excludes sample contamination;

c) delivered in a safe "ready to use" packaging, marked and labeled by the manufacturer with identification data (name, batch/serial number, validity terms, storage conditions). - The RFID readers are mounted inside the reagent loader shaft. The RFID tag contains the following information: the reagent pack name, lot number, expiry date, reagent container code…;

The offered devices:

cobas pro e 801 instrument - laboratory medical device – 2 (two), the number of tests, accessories / consumables / reagents / controls / solutions and other mandatory products, including related to the activity of the laboratory medical device, necessary in the process of laboratory examination of donated blood to:

1.HBsAg – 90 000 tests;

2. antibodies to hepatitis C virus (HCV) – 90 000 tests;

3. antibodies against Treponema Pallidum - 90 0000 tests;

4. HIV-1 p24 antigen and antibodies to HIV-1, including group O, and HIV-2 - 92 000 tests;

The technical service/repair of the medical devices, during the whole period of execution of the contract, by personnel authorized by the manufacturer will be assured.

1. Medical device – 2 pieces, cobas pro e801, year of production: new instruments, not older than 2023;

2. The e 801 analytical unit is a fully automated, high throughput immunology analyzer:

a) closed technology analyzer: Reagent pack type - *cobas e pack green*;

b) fully automated technology analyzer;

c) analyzer with electrochemiluminescent technology (ECL) used by the instrument is based on the reaction of a ruthenium complex with tripropylamine (TPA). The chemiluminescent reactions that lead to the emission of light from the ruthenium complex are initiated electrically. The advantage of electrically initiating the chemiluminescent reaction is that the entire reaction can be precisely controlled.

d) analyzer with the simultaneous identification technique of HBsAg markers, anti HCV antibodies, anti-Treponema Pallidum antibodies, HIV Ag/Ac and other markers according to the attached Parameter list.

3. Accessories/consumables/reagents/calibrators/solutions and other mandatory products required in the testing process are included - for 362 000 tests requested;

4. Sample loading capacity for testing:

a) loading capacity: 60 racks (300 samples);

b) the possibility of continuous loading starting from 1 (one) sample;

5. Test processing speed - up to 300 tests/h per each device;

6. Requirements to the functionality of the device:

a) loads/unloads racks automatically. Automatic reagent loading during Operation and Stand By;

b) automated pipetting for reagents/calibrators/solutions and samples. Software-supported management Colors indicate the status: Empty, Sufficient, Onboard stability, shelf life.

c) automatic dilutions: 1:1.1 to 1:27 000;

d) automatic waste disposal, including software-supported management (permanent waste inventory);

e) permanent monitoring of the status of the samples in the work list;

f) quality control (QC) system ensure quality analysis of the samples, reagents/calibrators/solutions;

The system informs if any alarm is issued during operation (visually and sonically);

g) provided with the specially designed mode for emergency tests: STAT port;

h) a database manages the sample records, calibration and QC data as well as system parameters and results;

i) most of the barcode readers use LED technology with low output power. One laser barcode reader is used in the sample upply unit;

k) provided with mobile barcode laser readers;

l) cobas system software is embedded in the laboratory IT setup;

7. Software database management system and its functionality:

a) Operating system: Windows 10. Monitor: 21.5" touch-screen LCD Monitor. Cobas link automatically updates software. Cobas e-library is updated daily via an automatic download from the remote service platform.

b) receiving/monitoring/printing in electronic form or by manual input of analysis results, quality control results, notifications and device maintenance events;

c) database storage capacity: sample records (routine/STAT/QC) 12 000 samples (including rerun tests); and reaction process data 12 000 samples;

d) to access the system, each operator and administrator needs a user ID and a password.

e) cobas link provides a secure remote connection for data transfer between the cobas systems in your laboratory and the remote service platform: statistical data from your system, to monitor performance, for QC management, and for service purposes;

f) possibility to mask reagent packs, tests, or analytical units;

g) the system allows to: generate, view or print reports, take a screenshot. During or after a run, you can view the results of selected patient samples and QC measurements.

8. Accessories related to the device but mandatory for the conditions of

its operation: the PC has a DVD-RAM drive and two USB ports accessible from the front door of the sample supply unit.

e) UPS with the capacity to ensure the electricity supply source for at least 60 minutes is offered - Smart UPS Online 6000VA/5400W;

f) a water filtration and deionization system is offered with a tank for at least 300 samples in testing: WSU II with accessories;

9. Location and conditions needed for installment:

a) Line voltage: 200-240 V, Line frequency: 50/60Hz +/- 10%;

c) Instrument dimensions: (m) 2,82 (L) × 2,32 (W) × 1,43 (H);

Immunoassay detection of hepatitis B surface antigen (HBsAg) - Elecsys HBsAg II

Purpose: Immunoassay for the in vitro qualitative determination of hepatitis B surface antigen (HBsAg) in human serum and plasma, including for screening of blood donations;

Application method in the test reaction:

a) closed type technology on cobas e 801

b) fully automated;

c) electrochemiluminescence immunoassay “ECLIA”;

Total duration of assay: 18 minutes.

Diagnostic product:

1) test for the screening of donated blood and intended for transfusion or as raw material for production preparations from human plasma, of a generation that will ensure the detection of:

a) in human serum/plasma;

b) qualitative of HBsAg;

c) mutations: detection of genetic variations of the HBV virus known in the world, including for Eastern Europe region. Elecsys HBsAg II assay was specifically developed to detect a multitude of mutants;

2) test with 100% sensitivity on blood donor samples (performance panels);

3) test with specificity not less than 99.98% on blood donor samples;

4) test with analytical sensitivity (detection limit) - up to 0.04 IU/ml.

Components accompanying the diagnostic product: all necessary components will be present, in quantities sufficient to apply the test in the test reaction, according to the instructions for use of the product.

Form of packaging: delivered in safe “ready to use” packaging, marked and labeled by the manufacturer with RFID identification data (name, batch/serial number, validity terms, storage conditions).

Identity data displayed on the box will coincide with those on the labels of each component of the set.

Immunoassay for detection of antibodies to hepatitis C virus – Elecsys Anti-HCV II

Purpose: in vitro diagnostic test for the qualitative detection of antibodies to hepatitis C virus (HCV) in human serum and plasma including the screening of blood donations.

Application method in the test reaction:

a) closed type technology on cobas e 801

b) fully automated;

c) electrochemiluminescence immunoassay “ECLIA”;

Total duration of assay: 18 minutes.

Diagnostic product:

1) test for the screening of blood donated and intended for transfusion or as raw material for production preparations from human plasma, of a generation that will ensure the detection of:

a) in human serum/plasma;

b) qualitative detection of antibodies to hepatitis C virus (HCV)

2) test with 100% sensitivity on blood donor samples;

3) test with specificity not less than 99.84% inclusive, on blood donor samples;

4) uses peptides and recombinant proteins representing HCV core, NS3 and NS4 antigens for the determination of anti-HCV antibodies, including at least 3 subtypes characteristic of the European region.

Components accompanying the diagnostic product: all necessary components will be present, in quantities sufficient to apply the test in the test reaction, according to the instructions for use of the product.
Form of packaging: delivered in safe "ready to use" packaging, marked and labeled by the manufacturer with RFID identification data (name, batch/serial number, validity terms, storage conditions).
Identity data displayed on the box will coincide with those on the labels of each component of the set.

Immunoassay for detection of total antibodies (IgG and IgM) to Treponema pallidum – Elecsys Syphilis

Purpose: in vitro qualitative determination of total antibodies to Treponema pallidum in human serum and plasma including the screening of blood donations.

Application method in the test reaction:

a) closed type technology on cobas e 801

b) fully automated;

c) electrochemiluminescence immunoassay "ECLIA";

The duration of the test process, including the incubation period - up to 18 minutes.

Diagnostic product:

1) test designed for the qualitative detection of antibodies to Treponema Pallidum in human plasma, used in screening of donated blood and intended for transfusion or raw material for the production of preparations from human plasma;

2) test with 100% sensitivity on blood donor samples;

3) test with specificity not less than 99.88% inclusive, on blood donor samples.

Components accompanying the diagnostic product: all necessary components must be present, in quantities sufficient to apply the test in the test reaction, according to the instructions for use of the product.
Form of packaging: the set delivered in secure packaging, marked and labeled by the manufacturer with the mention of data of identity (name, batch/serial number, validity terms, storage conditions). Identity data displayed on the box will necessarily coincide with those on the labels of each component of the set.

Immunoassay for simultaneous determination of HIV-1 p24 antigen and antibodies to HIV-1, including group O, and HIV-2 - Elecsys HIV Duo

Purpose: Immunoassay for the in vitro qualitative determination of HIV-1 p24 antigen and antibodies to HIV-1, including group O, and HIV-2 in human serum and plasma, including the screening of blood donations;

Application method in the test reaction:

a) closed type technology on cobas e 801

b) fully automated;

c) electrochemiluminescence immunoassay “ECLIA”;

Total duration of assay: 18 minutes.

Diagnostic product:

1) test for the screening of donated blood and intended for transfusion or as raw material for production preparations from human plasma, of a generation that will ensure the detection of:

a) in human serum/plasma;

b) simultaneous qualitative HIV-1 p24 Ag and anti-HIV1/HIV2 antibodies.

2) test with 100% sensitivity on blood donor samples;

3) test with specificity – 99.92 % and not less than 99.87% for blood donor samples;

4) test with analytical sensitivity (detection limit) – Antigen detection (HIVAG/HIVDUO) ≤ 1.0 IU/mL

Components accompanying the diagnostic product: all necessary components will be present, in quantities sufficient to apply the test in the test reaction, according to the instructions for use of the product.

Form of packaging: delivered in safe “ready to use” packaging, marked and labeled by the manufacturer with RFID identification data (name, batch/serial number, validity terms, storage conditions).

Identity data displayed on the box will coincide with those on the labels of each component of the set.

We remain at your disposal for any further clarifications

Kindest regards

Renata Popielecka

07-Nov-2024 | 20:49 CET

Emilian Dziemianczuk

06-Nov-2024 | 23:22 CET